

In re Application of: Tamar HAREL et al
Serial No.: 10/804,560
Filed: March 18, 2004
Office Action Mailing Date: December 8, 2008

Examiner: Michael William Kahelin
Group Art Unit: 3762
Attorney Docket: 34487

REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 52-55, 79-87, and 101-112 are in this Application.

All claims are rejected under 35 U.S.C. §102 or under 35 U.S.C. §103.

Claims 52-54, 82 and 104-106 are rejected under 35 U.S.C. §112.

Claims 52-54, 82, 85, 103-108 are amended herewith.

Claims 109-112 are new.

112 rejections

Claim 52 was rejected as the language “every period of time” was considered vague. The claim has been amended to remove this limitation. A similar limitation was reintroduced in claim 109, without the offending phrase.

Claim 53 was rejected as the language “in cases of doubt” is vague. The claim was amended to clarify what “doubt” is. It is argued that the scope of the claim has not changed. Similarly, the term “over-stimulate” has been amended and clarified.

Claim 54 was rejected as the language “relatively” was considered unclear. Applicants have amended the language to avoid the unclear language.

Claim 82 was rejected as the language “knowledge” was considered unsuitable/unclear for an apparatus. The claim has been amended with different language.

Claim 85, not rejected, was amended for antecedent basis of “field”.

Claim 104 was rejected for lack of antecedent for “said given period”. The claim was amended to depend on claim 109 and without the offending language.

Claim 105 was rejected for lack of antecedent for “said electric field”. The claim was amended to provide antecedent.

Claim 106 was rejected as it is unclear if the electrode is in addition to the electrode of claim 52 or a limitation thereon. The claim was amended to clarify this point.

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102 rejections

Claims 52-55, 79, 81-87, 103-104, 106-108 are rejected under 35 USC 102 over Wernicke US 5,231,988.

Referring first to claim 52, claim 52 has been amended by replacing the limitation of frequency of application with a limitation on the electrode being configured to be mounted attached to muscle tissue. In distinct contrast, the cited art (Wernicke) teaches an electrode that coils around a nerve (See Fig. 3, col. 10, lines 30-65, for example). As the whole purpose of the cited art is to selectively stimulate nerves, the cited art would not use a different electrode design and would not attach an electrode to muscle, as this would reduce from the electrodes effectiveness and possibly allow the electrode to migrate relative to the nerve. Claim 109 reintroduces a limitation similar to that removed from claim 52 and the dependencies of some claims was switched accordingly from claim 52 to claim 109.

Referring to claim 53, which was amended for clarity, applicants respectfully disagree with the Examiners position. The cited art, as any art which works by stimulation of insulin secretion, is concerned with avoiding hypoglycemia, which can incapacitate or kill a patient. As such, over stimulating (stimulating more than needed) is avoided so as not to cause hypoglycemia. Applicants also note that closed loop systems, in general, attempt to provide efficiency by approaching a target and not by overshooting thereof. Applicants also suggest that the Examiner's interpretation cannot be applied to the amended claim, as clarified. This can be seen by examining Col 7 line 42 and through Col. 8, line 22, where care with respect to selecting a stimulus is described.

Referring to claim 79, applicants respectfully disagree. The whole application (e.g., Col 8, lines 1-22, Col 9, lines 40-60) teach that the effect of the electric field is to cause insulin secretion. This is in distinct contrast to the clear meaning of claim 79, that the effect of the field is not mediated by insulin secretion.

Referring to claim 82, applicants respectfully submit the Examiner has misunderstood the art. Wernicke, at col. 8 lines 3-16 seems to be describing a user

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using an external wand to indicate to the system what food was eaten so the system can apply (lines 17-22) a suitable stimulus which will cause suitable insulin secretion. There is no discussion therein that a user indicate to the system that a slow acting chemical based insulin therapy is provided to the pancreas.

Referring to claim 87 (and 106), applicants have noted above that the cited art teaches specifically attaching the electrode to nerves and such attachment is not suitable for muscles. Col. 11, lines 3-6 teach that a same attachment method is used near the stomach (a muscular organ). New claims 110 and 111 further elaborate on muscular organs in the abdominal cavity.

Referring to claim 107, applicants respectfully do not understand the Examiner's position. The stomach is always active electrically and eating events have a myriad of effects thereon. Nevertheless, claim 107 has been clarified so it is clear that the synchronization is with specific electrical activity, e.g., propagation of action potentials.

Referring to claim 108, while the Examiner could be right that the system of Wernicke can be used to only reduce abnormal glucose levels and not reduce normal levels, claim 108 is directed at the properties of the field, not the system. In claim 108 a same field reduces high glucose levels and does not substantially reduce normal blood levels. New claim 112 is also directed to a generally similar subject.

103 rejections

Claims 80, 101-102 and 105 are rejected under 35 USC 103 over Wernicke. Applicant respectfully disagrees.

With respect to claims 80 and 105, applicants object to the Examiner's use of "well known". If an idea is well known, there should be at least official notice taken, or, more preferably, a specific document used, so that the applicant can argue that what is taught in that document cannot be combined with Wernicke to meet the claim limitations. Wernicke does not even hint that affecting glucagon and/or preventing burst activities could be possible or desirable. In such a sensitive situation of controlling complex biological systems, applicants submit that more than a statement

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of "well known" is needed to justify to a person of the art the modification of a working method in some untested manner. As an example, Houben (previously cited and argued against) may teach applying a field which does not provide induce new bursts (in certain cases), but such field is applied to pancreatic tissue, not vagus nerves. It is not clear based on a reading of the cited art, how such a field would interact with concurrent stimulation of the vagus nerve. Moreover, why implant two sets of electrodes, in two different organs, when each of the arts believes that one set is enough?

Referring to claim 102, applicant respectfully submits that if the mechanism of the art is insulin based, insulin levels are increased for a glucose ingestion event and not reduced as claimed.

Double patenting rejection

All claims are rejected under a provisional obviousness type double patenting rejection over claim 10 of application 10/526,708 and claim 10 of 10/570,576, in view of Wernicke. It is believed that the claim amendments overcome this problem.

Conclusion

The dependent claims not specifically argued are patentable at least for reason of being dependent on a patentable independent claim.

In view of the above amendments and remarks it is respectfully submitted that claims 52-55, 79-87, and 101-111 are now in condition for allowance. A prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,



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Enclosures:

- Petition for Extension (Two Months)
- Additional Claims Transmittal Sheet